

<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number <b>Q94512</b>
Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number <b>10/577,132</b>	Filed <b>August 28, 2006</b>
	First Named Inventor <b>Patrice RICHARD</b>	
	Art Unit <b>3761</b>	Examiner <b>Susan Shan SU</b>
<p style="text-align: center;">WASHINGTON OFFICE <b>23373</b> CUSTOMER NUMBER</p>		
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal</p> <p>The review is requested for the reasons(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p><input checked="" type="checkbox"/> I am an attorney or agent of record.</p> <p>Registration number <u>59,561</u></p> <p style="text-align: right;"><u>/Dion R. Ferguson/</u> Signature</p> <p style="text-align: right;"><u>Dion R. Ferguson</u> Typed or printed name</p> <p style="text-align: right;"><u>(202) 293-7060</u> Telephone number</p> <p style="text-align: right;"><u>March 1, 2010</u> Date</p>		

**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q94512

Patrice RICHARD

Appln. No.: 10/577,132

Group Art Unit: 3761

Confirmation No.: 8183

Examiner: Susan Shan SU

Filed: August 28, 2006

For: PLACENTAL-BLOOD EXTRACTION DEVICE

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

**MAIL STOP AF - PATENTS**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Pursuant to the Pre-Appeal Brief Conference Pilot Program, and further to the Examiner's Final Office Action dated September 1, 2009, Applicant files this Pre-Appeal Brief Request for Review. This Request is also accompanied by the filing of a Notice of Appeal.

Applicant turns now to the rejections at issue. In the Amendment filed December 1, 2009, claim 1 was amended to incorporate the subject matter of claim 11. This Amendment was entered by the Examiner in the Advisory Action dated December 9, 2009. Accordingly, the following arguments are directed toward the rejection of claim 11, which would now be applicable to claim 1.<sup>1</sup> More particularly, the Examiner alleges that a proposed combination of Deverre, Dracker and Seddon would render claim 1 obvious.

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<sup>1</sup>The rejections set forth in the Final Office Action are as follows: 1. Claims 1, 3-7, 9, and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Deverre (US Patent 7,131,958) in view of Dracker (US Patent 5,356,373). 2. Claims 2, 11, 12, 18, and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Deverre in view of Dracker as applied to claim 1 above, and further in view of Seddon et al. (US Patent 6,024,731). 3. Claims 13-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dracker in view of Seddon. 4. Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Deverre and Dracker as applied to claim 7 above, and ... (footnote continued)

Applicants respectfully submit the Examiner's proposed combination of Deverre, Dracker and Seddon does not render claim 1 obvious. First, Applicants respectfully submit that there is no predictability that the Redon-type bottle disclosed in Seddon would provide a sufficient vacuum for a blood collection device, as disclosed in Deverre and Dracker. Second, the low vacuum supplied by a Redon-type bottle would teach away from combination with the blood collection devices disclosed in both Deverre and Dracker. Third, Applicants submit that combining Deverre and Seddon as alleged by the Examiner would not have resulted in the claimed subject matter. Finally, Applicants submit that combining a Redon-type bottle with a blood collection systems has strong secondary considerations for patentability, as the combination has never been proposed, which indicates that the combination of elements outlined in claim 1 is inventive.

The Examiner acknowledges that Deverre fails to disclose suction means connected to at least one needle.<sup>2</sup> The Examiner alleges that Dracker discloses this feature, and that it would have been obvious to combine Deverre and Dracker. However, the Examiner concedes that the proposed combination of Deverre and Dracker fails to disclose that "the suction means comprises a vacuum bottle that simultaneously forms a collection bottle," as recited in claim 1.<sup>3</sup> The Examiner argues that Seddon discloses this feature, and that the proposed combination of Deverre, Dracker and Seddon renders claim 1 obvious.

Dracker discloses a flexible collection bag attached to the needle, wherein a vacuum is applied to the flexible collection bag, further providing suction through the needle (col. 4, l. 45-53). This vacuum is applied from a separate device other than the flexible collection bag. Claim

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further in view of Darling, Jr. (US Patent 6,213,986). 5. Claim 10 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Deverre and Dracker as applied to claim 1 above, and further in view of Van Der Heiden et al. (US Patent 5,879,318).

<sup>2</sup> Final Office Action mailed September 1, 2009, page 3.

<sup>3</sup> *Id.* at page 5.

1, on the other hand, recites that “said suction means comprises a vacuum bottle that simultaneously forms a collection vessel.”

As argued in the pre-appeal brief request for review submitted February 18, 2009, Applicants submit that it would not have been obvious for one of ordinary skill in the art to replace the active suction device (using an applied vacuum) disclosed in Dracker (or a simple syringe, which also requires an applied vacuum to create the suction), with a Redon-type bottle such as the passive device disclosed by Seddon, particularly given that Seddon relates to a wound drainage system.

In the Response to Arguments detailed on page 2 of the Final Office Action, the Examiner argues that Seddon is an active system, and disagrees that the vacuum bottles referenced in Seddon have no “accelerating” effect. Rather, the Examiner concludes that suction would necessarily result in quicker removal of a fluid when compared to a system that does not use suction, such as Deverre which uses gravity. However, Applicants respectfully submit that this conclusion is misplaced. The Examiner is not comparing a device with suction to a device without suction in the same application (e.g., blood collection). Thus, the Examiner’s comparison of the device in Deverre with the device in Seddon is not on point.

In a blood collection device, blood flows much quicker out of the body than in a wound drainage system. Even without suction, which is disclosed in Deverre, blood flows rather quickly out of the veins (in particular due to pressure provided in the subject’s body), and the blood collection is done in a short period of time (several minutes). According to wound drainage systems, however, the object is to remove the fluids which appear at a wound site over several days. Without suction, these fluids would remain inside the wound, and the suction is only provided to remove these fluids from the wound. Collection of these fluids is not desired to be performed as quickly as possible, and in reality, the suction should be as low as possible. Thus, there is no indication or predictability that a Redon-type bottle, as disclosed in Seddon, would be useful in a blood collection device, given that Redon-type bottles supply extremely low vacuums.

Further, the use of a Redon-type (vacuum) bottle would teach away from the combination with blood collection systems as disclosed in Deverre and Dracker. The use of the vacuum bottle in a wound drainage system (slowly collecting fluids which otherwise would remain in the wound) is fundamentally different from the use of suction in a blood collection system (accelerating the blood collection to improve quantity and quality of the collected blood). Accordingly, one of ordinary skill in the art, trying to improve a blood collection system, would not consider using the Redon-type vacuum bottle disclosed by Seddon, which relates to wound drainage. Additionally, the disclosure in Dracker of a separate vacuum source teaches away from the use of a Redon-type bottle as a vacuum source in a blood collection application.

Additionally, Applicants submit that combining Deverre and Seddon as alleged by the Examiner would not have resulted in the claimed subject matter, as the addition of the vacuum bottle disclosed in Seddon would not actually apply a vacuum to the system of Deverre. Specifically, Deverre uses a rinsing solution containing an anticoagulant and/or preservative to rinse the tubes of the collection device prior to blood collection. This anticoagulant/preservative is collected in the same collection bag as the umbilical cord blood. Accordingly, once the vacuum bottle would be opened, the bottle would fill with anticoagulant/preservative prior to the collection of the umbilical cord blood. The filling of the bottle with anticoagulant/preservative would slow/eliminate the vacuum applied to the desired umbilical cord blood. Thus, the Examiner's proposed combination of Deverre and Seddon would not apply a suction for sucking the placental blood so as to feed said collection vessel.

Finally, Applicants submit that combining a Redon-type bottle with a blood collection systems has strong secondary considerations for patentability, as the combination has never been proposed, which indicates that the combination of elements outlined in claim 1 is inventive. Applicants note that several suction systems are known which may be used for blood collection (e.g., a syringe or Dracker's flexible bag, submitted to vacuum), and each of these systems require a specific application of a vacuum to provide said suction. Applicants also note that Redon-type vacuum bottles have been in existence for many years, and are well-known in the field of wound drainage. However, while the use of a Redon-type vacuum bottle is well known

for wound drainage and collection, a Redon-type vacuum bottle has never been considered in connection with blood collection systems, due to its normal use of minimal vacuum to provide wound drainage slowly, over several days time.

**Conclusion**

Therefore, for the reasons set forth above, Applicants submit the Examiner's proposed combination of references would not render independent claim 1 obvious. Independent claim 13 recites "wherein the vessel creates the vacuum." Independent claim 17 recites "wherein the collection vessel is of the Redon type." The prior art does not teach or suggest these combinations of features as explained above and in Applicants' previous responses. Each of the dependent claims, 2-10, 12, 15, 16 and 19 are patentable at least by virtue of their respective dependencies from claims 1, 13 and 17.

Respectfully submitted,

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WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: March 1, 2010

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